## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-9, 17, 18, 21 and 22, are drawn to a method of diagnosis or assessing ex-vivo the titer of fertility-relevant autoantibodies of a mammalian female.

Group 2, claim(s) 10-15, 19 and 23-25, are drawn to an oligo-peptide, polypeptide, a pharmaceutical composition comprising the same and a kit comprising the same.

Group 3, claim(s) 16, is drawn to a method of treating fertility disorders comprising administering a medicament comprising an oligo-peptide or polypeptide.

Group 4, claim(s) 20, is drawn to a method for contraception or induction of inducing sterility comprising administering an oligo-peptide or polypeptide to a patient in need thereof.

The inventions listed as Groups 1-4 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A. Group 1, requires the special technical features of diagnosis or assessing ex-vivo the titer of fertility-relevant autoantibodies of a mammalian female, which is not required for the methods of Groups 3-4.

B. Group 2, requires the special technical features of an oligo-peptide, polypeptide, a pharmaceutical composition comprising the same and a kit comprising the same.

C. Group 3, requires the special technical features of treating fertility disorders comprising administering a medicament comprising an oligo-peptide or polypeptide, which is not required for the methods of Groups 1 and 4.

D. Group 4, requires the special technical features of contraception or induction of inducing sterility comprising administering an oligo-peptide or polypeptide to a patient in need thereof, which is not required for the methods of Groups 1 and 3.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01

***Further Restriction/Election***

**Groups 1-4**

If Group 1, 2, 3 or 4 is elected, a further restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:

The inventions Groups 1-4 pertain to a number of oligo-peptides or polypeptides listed in claims 8, 10, 12, 14, 15, 18 and 20 (i.e., SEQ ID NO: 1, 2, 3....7, and 8; and PAPP-A, ADAM-TS 13).

Each of the claimed oligo-peptides or polypeptides are composed of amino acid units and are structurally distinct molecules. Each sequence requires a unique separate search of the prior art. Searching two claimed sequences would constitute an undue burden on the examiner and the USPTO's resource because of the non-coextensive nature of these searches. **Therefore, Applicant must choose 1 oligo-peptide or polypeptide (from SEQ ID NO: 1, 2, 3....7, and 8; and PAPP-A and ADAM-TS 13) against which the search should be performed.**

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

**If applicant elects Group 1, 2, 3 or 4, a single oligo-peptide or a single polypeptide must be elected to be fully responsive. It is noted that the election of an oligo-peptide or polypeptide of Group 1, 2, 3 or 4 is a restriction election and not a species election.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GYAN CHANDRA whose telephone number is (571)272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gyan Chandra
Art Unit 1646
26 May 2008
Fax: 571-273-2922

/Robert Landsman/
Primary Examiner, Art Unit 1647